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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/839,194	02/20/1992	KATHERINE GORDON	G0744.70042US07	6108

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EXAMINER

MONTANARI, DAVID A

ART UNIT	PAPER NUMBER
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1632

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

07/839,194

Applicant(s)

GORDON ET AL.

Examiner

David Montanari

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants arguments and amendments filed 2/9/2007 have been entered.
2. The rejection of claims 19-22, 24-27 and 29 under 35 USC 102(a) is withdrawn.
3. Claims 1-2, 5-8, 11, 16-17, 19-22, 24-27 and 29 are examined in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 19 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons of record in the office action mailed 8/7/2006.

Response to Arguments

Applicants argue in amendment filed 2/9/2007 that the phrase the Examiner alleges is not provided in the description of the instant specification is in fact disclosed in the original specification on pg. 5 lines 18-22. Applicants continue to argue that the beginning of the paragraph which provides this description discloses that promoters can be isolated from milk protein genes, making clear that the "putative promoter" can be a milk promoter. This is not

persuasive. While this can be a milk promoter, this can also be any other promoter other than a milk promoter. As discussed in the previous office action, the specification fails to describe or contemplate fragments or combination of fragments that provide transcriptional control. Claim 19 is broader in scope than claim 1, however the instant specification fails to support this scope following the amendment of claim 19. There is no description in the instant specification that supports any description of functional fragments that would have promoter activity other than the disclosed milk promoter. Lines 18-22 on pg. 5 do not support the scope of amended claim 19 and thus for reasons of record and above the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 5-7, 11, 16, 17, 19-22, 24-26 and 29 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record in the office action mailed 8/7/2006.

Response to Arguments

Applicants argue in amendment filed 2/9/2007 that one of ordinary skill in the art would clearly understand the use of the term “naturally” based on the plain meaning of the term and the context of the claims. Applicants continue that the use of the term is exemplified in the instant specification and point to several places in the specification to where the term is used. This is not

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persuasive. At issue is the question what is a natural promoter? The claimed DNA construct comprises a gene that is under the control of a promoter that does not naturally control said gene. However it is the "nature" of promoters to control things, i.e. start transcription. That is all that they do. What is being claimed, a promoter sequence which does not naturally control transcription of a gene is counterintuitive, promoters by nature want to control transcription. The claimed mammalian milk protein promoter sequence will and has been shown to control many different types of genes, it is its nature to do so. Applicants argue that the ordinary artisan would readily understand the term "naturally" in the context of the claimed invention, however this is not the case when the claim is examined for its entire breadth of the claimed subject matter. Thus for reasons of record and above the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,727,405 for reasons of record in the office action mailed 8/7/2006.

Claims 1, 2, 5-8, 11, 16, 17, 19-22, 24-27 and 29 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-41 of U.S. Patent No. 7,045,676 for reasons of record in the office action mailed 8/7/2006.

Response to Arguments

Applicants argue in amendment filed 2/9/2007 that when the claims are in otherwise allowable form, Applicant will file a terminal disclaimer at that time. This is not persuasive. A statement of acquiescence over a pending rejection does not overcome the rejection and thus the double patenting rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-7, 11, 16, 17, 19-22 and 24-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Qasba et al. (1984, Nature, Vol. 308, pgs. 377-380) for reasons of record in the office action mailed 8/7/2006.

Response to Arguments

Applicant argue in amendment filed 2/9/2007 that Qasba et al. does not teach all the elements of the rejected claims. Applicants continue that Qasba does not teach the elements of a mammalian milk promoter which does not naturally control transcription of said gene. Applicants continue to argue that Qasba teaches a nucleotide sequence of the rat alpha-lactalbumin gene including its promoter sequence and that a fragment of the promoter sequence is allegedly described by Qasba and allegedly would result in an expression profile different from the "natural" expression profile. Applicants continue that this explanation is not sufficient to sustain the rejection. Applicant states they cannot deduce from Qasba's teachings that this alleged fragment is a mammalian milk promoter which does not naturally control transcription of said gene or is a sequence that controls the transcription and is upstream from the transcriptional start site of a mammalian milk protein and which does not naturally control the transcription of said gene. In addition, Applicant states they cannot deduce from Qasba's teachings that a construct that falls within the scope of the rejected claims is even provided.

These arguments are not persuasive. At issue is the term "naturally" when the teachings of Qasba are applied in the instant art rejection. However the fragment of a promoter sequence is not natural relative to a full-length promoter. A natural promoter sequence would be the entire

sequence intact that results in transcription at 100% efficiency relative to said natural promoter.

The promoter fragment taught by Qasba is not a full-intact promoter, and is missing some nucleotide regions, however it will still promote transcription, but in a way that can be termed "unnatural". The ordinary artisan can conceivably anticipate that this promoter fragment can function at less than 100% transcription efficiency compared to the full-length intact promoter, for example at 50% or 70% transcription efficiency. In this comparison this would be an unnatural behavior of the promoter fragment and the teachings of Qasba anticipate this.

Applicants argue that the sequence taught by Qasba is not a construct. Again this is not persuasive. A construct is a circular piece of DNA, however Qasba represents the data linearly to illustrate sequences of importance. For the purposes of amplification alone this sequence must have been in construct form to provide the data taught by Qasba. Thus for reasons of record and above the rejection is maintained.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Montanari whose telephone number is 1-571-272-3108. The examiner can normally be reached on M-Tr 8-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 1-571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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